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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,190	03/02/2000	John Edward Hesketh	0623.0820001/REF	4790

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 04/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/518,190

Applicant(s)

HESKETH ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-16 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. Amendment C, filed 1/29/02, has been entered into the record.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Answer to Traversal

A. Claims 9-16 and 21 were subject to restriction in Paper No.11. In Paper No. 13 Applicants elected Group I, claims 9 in part, 10-16 and 21 with traverse. Applicants argue that if the nucleic acid molecule of claim 9 is found to be novel and unobvious, then dependent claim 15 should be novel and unobvious. While this is true, the issue lies not in the recitation in claim 15 that the claimed cell is found in cell culture, but that the cell of claim 15 can be found in a non-human animal. This implies that the polynucleotide of claim 9 would be used to produce transgenic animals. The Examiner apologizes for possibly confusing the issue since the Office Action states that claim 15 recited "non-human animal *cell*," but the claim obviously read "non-human animal." Claim 15 will be examined insofar as it reads on "cells in culture." It is required that Applicants remove the recitation of non-human animal from the claim, as the scope and issues regarding subject matter involving transgenic animals are in conflict with examination of the remainder of the claimed invention.

3. Claim Objections

- A. The title remains objected to for the reasons already of record on page 3 of the Office Action dated 10/29/01. This issue will be addressed if the claims of the present application are found allowable.
- B. Claim 15 is objected to since it recites "non-human animal," which is not being examined as part of the claimed invention. Applicants are required to remove this limitation from the claim.

4. Claim Rejections - 35 USC § 112, second paragraph

- A. The previous rejection of claim 16 under 35 USC 112, second paragraph, has been withdrawn since Applicants have amended the claims to recite "purifying the protein."

5. Claim Rejections - 35 USC § 103

A. Claims 9-16 remain rejected under 35 USC 103 as being unpatentable over Lee. et al. in view of Kordula et al. Applicants argue that there is no motivation to modify the nucleic acid of Lee et al. and that the nucleic acid molecule of Lee et al. is naturally directed to the ER. They also argue that the motivation of producing large quantities cannot be obvious based on hindsight and there must be teachings to look to particular sources and elements. Applicants also argue that the molecule of Kordula et al. is expressed in a prokaryotic system, not a eukaryotic system as claimed by the present invention and that the molecule was obtained through sonication, not secretion. Finally, they argue that Kordula et al. do not teach anything about requirements for expression in mammalian cells.

These arguments have been considered, but are not deemed persuasive. First, the issue is not that the nucleic acid molecule of Lee et al. is directed to the ER, since this molecule is being substituted with the nucleic acid molecule of Kordula et al. The basis for this rejection lies in the fact that the molecule of Kordula et al. is an intracellular (cytosolic) protein which cannot be secreted from mammalian cells (page 192, left column, 4th full paragraph). Kordula et al. also teach that expression of HLEI cDNA in E. coli led to the accumulation of large amounts of the protein in the cytoplasm and inclusion bodies of these prokaryotes (page 192, right column, first full paragraph) and that expression of HLEI will really only be of use after large-scale purification which may require the use of a more efficient expression vector (page 192, right column, second full paragraph).

Lee et al. teach an efficient expression vector for use in secreting and purifying proteins from mammalian cells (Abstract). They have joined, in-frame, a sialyltransferase to be secreted. Contrary to Applicants' arguments, regardless of the "normal" targeting of sialyltransferase, the cDNA encoding this protein is not the basis of this rejection, only the expression vector containing the signal peptide. Therefore, based on the need for a better expression vector and large-scale purification for the protein of Kordula et al., one of ordinary skill in the art would have been motivated to substitute the cDNA of Kordula et al., which has the 3'-UTR deleted, for the nucleic acid encoding the sialyltransferase in the vector of Lee et al. for the purpose of producing purified protein on a large-scale, which cannot necessarily be accomplished using the vector and expression system of Kordula et al.

Furthermore, as stated in the previous rejection Maeda et al. teach the use of the signal peptide from albumin in order to express large quantities of protein (Abstract). It would have been obvious to one of ordinary skill in the art to have substituted the albumin signal sequence of Maeda et al. for the signal peptide of Lee et al. for the purpose of producing a fusion protein which can be secreted since it was well-known at the time of the invention that albumin is secreted from mammalian cells and that the use of

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albumin signal sequence is capable of generating large (even "mass") quantities of secreted protein (see Conclusion). Therefore, depending various factors, such as availability of particular vectors and purification methods (Western blot vs. affinity chromatography), the artisan would have various signal peptides from which to choose to allow secretion of the desired protein. The artisan would have been motivated to use the signal sequence from albumin since this sequence has been shown to generate large (even "mass") quantities of secreted protein, as would be desired from the artisan.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Advisory information

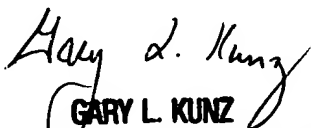
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
April 08, 2002


GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600